

## REMARKS

This amendment is submitted in response to the Final Office action mailed August 22, 2007, in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on November 22, 2007. Submitted herewith is a Petition for a Two-Month Extension of Time extending the due date to January 22, 2008. Accordingly, this amendment is timely submitted.

### I. The Pending Claims

Claims 1, 5-8, 10-11 and 26, of which claim 1 is independent, remain pending. Claims 2-4, 9, 12-17 and 18-25 are cancelled. Applicant reserves the right to pursue these claims in a divisional or continuation application. Applicant does not acquiesce in the correctness of the rejections or objections and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Applicant thanks the Examiner for acceptance of the Sequence Listing and reinstatement of claim 26 for reconsideration.

Independent claim 1 is amended, support for which is found throughout the specification, particularly at column 3, paragraphs [0033] and [0041]; and column 4, paragraphs [0047] – [0048] of the instant published patent application (U.S. Patent Application Publication No. 2004/0131659 A1), as well as the Examples provided therein. No new matter has been introduced in these amendments; Applicant therefore requests that all amendments be entered at this time and reconsideration of this application in view of the above amendments and the following remarks be made.

Applicant has amended independent claim 1 by incorporating the subject matter of dependent claim 3, thereby cancelling claim 3. Claim 1 is amended as follows: (1) inserting the phrase "an oligosaccharide blend that comprises" between the terms "comprising" and "fructo-oligosaccharide (FOS);" (2) inserting the phrase "(a) each of said" between the terms "wherein" and "FOS" (second occurrence); (3) inserting the phrase "and said GOS" between the terms "FOS" (second occurrence) and "contains" (first occurrence); (4) deleting the phrase "and said

GOS contains up to about 95% by weight of oligofructose composed of chains with a degree of polymerization ranging from about 2 to about 7" after the phrase "degree of polymerization ranging from about 2 to about 7 and" (first occurrence); (5) inserting the phrase "; (b) the weight ratio of FOS and GOS is from about 0.5 to about 20;" before the phrase "and the FOS and GOS are capable of synergistically...;" and (6) incorporating the term "(c)" between the term "and" and before the phrase " the FOS and GOS are capable of synergistically...."

To correct a clerical error in claims 5-8, 10-11 and 26, a comma has been inserted after the preamble and, in some instances, the phrase "in which" or the term "which" has been replaced with the term "wherein" or the phrase "wherein the composition."

In claim 6, a space has been added between the terms "400" and "kcal."

With respect to claim 26, the term "comprising" has been substituted with the term "comprises."

Applicant submits that the rejections based on lack of novelty and obviousness are overcome in view of the amendments and arguments presented in the response. Accordingly, entry of these amendments is requested.

## II. Rejection Under 35 U.S.C §102(b)

At pages 2-4 of the Office Action, the Examiner rejected claims 1, 3, 5-8 and 11 under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 6,399,124 to Lesens et al. (referred hereinafter as "Lesens"). According to the Examiner, Lesens "teaches composition comprising fermentable fibers specifically promoting the growth, in the intestinal tract, of the lactic acid bacteria contained initially in the ice cream...." In addition, Lesens "teaches the composition contains prebiotic fibers (abstract), which may be of a protein or saccharide nature, chosen from vegetable pectins, chito-, fructo-, gentio-, galacto-, isomalto-, manno- or xylo oligosaccharides, etc.... The preferred galactooligosaccharides comprise a saccharide part of 2 to 5 repeating units and preferred fructooligosaccharides are inulin-oligofructoses extracted from chicory...." The Examiner cited Lesens' Examples 4 and 5 to assert that Lesens teaches "a cone made of Raftilose L30 (Table 7) or wafer dough of galactooligosaccharide P7L, respectively; and a decoration or coating such as that of Table 3 (galactooligosaccharide P7L) or Table 4 (Raftilose L30) Such a ratio would yield a weight ratio of 1.56 FOS:GOS in the single food composition." Furthermore,

the Examiner, based upon Lesens' disclosure of Examples 1 and 2, contended that "all examples of Lesens are compositions that are ready-for-consumption and high in calories," as that of the instantly claimed invention. Office Action at pages 3-4.

Applicant respectfully traverses the rejection.

Contrary to the Examiner's assertions, the presently claimed invention, as recited in amended independent claim 1, as well as the claims that are dependent therefrom, relates to a composition comprising an oligosaccharide blend that comprises fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein (a) each of said FOS and said GOS contains up to about 95% by weight of oligofructose composed of chains with a degree of polymerization ranging from about 2 to about 7; (b) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (c) the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the a sum of their individual prebiotic properties.

The subject matter of claim 3 has been incorporated into independent claim 1. Accordingly, the cancellation of claim 3 renders the rejection of this claim moot.

Applicant respectfully submits that Lesens fail to disclose or suggest a single food or ready-for consumption composition that is an oligosaccharide blend of fructooligosaccharide and galactooligosaccharide. On the contrary, Lesens, as illustrated in her Examples, describes the use of single compositions that included either a fructo-oligosaccharide (Example 1, Tables 2 and 4; Example 4, Table 7) or a galacto-oligosaccharide (Example 1, Table 3; Example 5)

The Examiner, at page 5 of her Office Action, stated that the weight ratio of FOS:GOS in Lesens' compositions is 1.56. Applicant respectfully disagrees with this ratio since in Lesens, the fructo-oligosaccharide and galactooligosaccharide are not added in combination in a single composition. As illustrated in her Examples, Lesens either added one or the other but not both as combination. In fact, such disclosure is not found elsewhere in the Lesens' reference. Nor is there any discussion of any weight ratios of FOS:GOS in Lesens. Lesens did not contemplate a pharmaceutical blend of FOS and GOS, particularly, when its particular approach for improving prebiotic activity is to increase the quantity of the prebiotic fibers in the her composition. As noted by Lesens, "it has been observed that the more solid concentrate of fibers that the diet contains, the more the intestinal transit of these fibers is retarded, with corresponding positive

influence on the development of the lactic acid bacteria in the intestine." Lesens at Column 5, lines 23-36. What is disclosed instead by Lesens is the "combined use of lactic acid bacteria and prebiotic fibers" for preparing frozen composition in which "the lactic acid bacteria and the fibers are not substantially in contact with each other." Lesens at column 7, lines 14-18.

Based on the foregoing remarks and claim amendments, Applicant respectfully submits that Lesens is not an anticipation-defeating reference since it fails to teach or suggest every feature of the claimed invention. Accordingly, Applicant requests the Examiner to reconsider and withdraw her rejection of claims 1, 3, 5-8 and 11 under 35 U.S.C. § 102(b).

### III. Rejection Under 35 U.S.C §103(a)

On page 5 of the Office Action, the Examiner rejected claims 1, 5 and 10 under 35 U.S.C. §103(a), as being unpatentable over Lesens. In particular, the Examiner asserted that Lesens "teaches the composition wherein the edible support alone comprises between 1 to about 60% milk, between about 0.5% to about 5% of animal or vegetable proteins, between about 0.1% to about 10% fibers, between about 15% to about 30% sucrose and between 2% to about 20% fat, by weight (claim 9)...." Thus, according to the Examiner, it "would have been obvious to one of ordinary skill at the time of the invention was made to look to Lesens to make a composition," as instantly claimed.

Applicant respectfully traverses the rejection.

As remarked above, Applicant respectfully submits that Lesens fail to neither describe nor suggest a single composition that employs a pharmaceutical blend of FOS and GOS, such as the composition set forth herein amended claim 1.

In fact, Applicant respectfully submits that Lesens fails to disclose compositions containing a combination of FOS and GOS. As discussed earlier, Lesens' intention is to increase the quantity of prebiotic fibers in her composition and even acknowledged the drawback of having higher quantities of pre-biotic fibers due to induction of "an unpleasant feeling of heaviness in the stomach." Lesens at column 5, lines 23-26.

As noted in Applicant's response to the previous Office Action, dated August 10, 2007, the specification discloses that the "prebiotic properties of FOS are significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive, i.e., a synergistic

effect in promoting the growth of beneficial bacteria, such as *Bifidobacteria* and *Lactobacilli*." See page 1, paragraph [0012] of the published application. In addition, the claimed combination of FOS and GOS in a single composition, with its unexpected synergistic effect, avoids the limitations identified by Lesens. Therefore, "as a result of this synergy, it is possible to obtain an equivalent or improved pre-biotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See page 1, paragraph [0013] of the published application.

For the reasons provided hereinabove and claim amendments as presented herein, Applicant respectfully asserts that the composition of the presently claimed invention, drawn to independent claim 1 and currently pending dependent claims 5 and 10, would not have been obvious to one of ordinary skill in the art. Lesens fail to describe or suggest a composition having an oligosaccharide blend of FOS and GOS, wherein the weight ratio FOS:GOS is from about 0.5 to 20 and wherein such combination has a synergistic effect at lower FOS dosages. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw her rejection of claims 1, 5 and 10 under §103(a).

On pages 6-8 of the Office Action, the Examiner rejected claims 1, 3, 5, 7-8 and 10-11 under 35 U.S.C. §103(a), as being unpatentable over J. Pediatric Gastroenterology and Nutrition, Volume 34, pages 291-295 to Moro et al. (referred hereinafter as "Moro"); Arch. Dis. Child Fetal Neonatal. Ed., Volume 86, pages F178-F181, 2002 to Boehm et al. (referred hereinafter as "Boehm"); and *Pediatrica*, Vol. 21, Nov/Dec, pages 39-48, 2001 to Rigo et al. (referred hereinafter as "Rigo"), all in view of Lesens.

According to the Examiner, Moro, Boehm and Rigo each "disclose infant formula comprising a combination of galactooligosaccharides (GOS) and fructooligosaccharides (FOS), fat, and protein." In particular, the Examiner contended that the infant formulas of Moro, Boehm and Rigo contain "oligosaccharide mixture [that] can comprise between 90% and 10% FOS," which "satisfies the weight ratio of FOS:GOS of about 0.1 to about 50" and can also "comprise between about 0.05 to about 40% by weight, based on total formulation." However, both Moro and Boehm "do not teach a composition comprising more than 1 g of protein in 100 kcal.

However, this deficiency is cured by Rigo, who discloses that "over 1% of protein can be present per 100 kcal." Thus, as formulated, the Examiner contended that the "formula" advanced by Moro, Boehm and Rigo are "nutritionally complete" and "ready-for-consumption."

Besides the above disclosures, Moro, Boehm and Rigo "do not teach the exact percentages of ingredients and ratio of FOS and GOS," as claimed in the present invention. However, the ratios and percentages, according to the Examiner, are disclosed by Lesens. Accordingly, the Examiner asserted that "it would have been obvious to one of ordinary skill in the art" to look into the disclosures of Moro, Boehm and Rigo, in view of Lesens, to make the claimed composition. In addition, one of ordinary skill in the art would be motivated to experiment and optimizes values to obtain workable ranges to treat those with gastrointestinal disorders, to promote the growth, in the intestinal tract..." (Office Action at page 8, first full paragraph). Applicant respectfully traverses the rejection.

At the outset, independent claim 1, as amended, now recites a composition comprising an oligosaccharide blend that comprises fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein (a) each of said FOS and said GOS contains up to about 95% by weight of oligofructose composed of chains with a degree of polymerization ranging from about 2 to about 7; (b) the weight ratio of FOS and GOS is from about 0.5 to about 20; and (c) the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the a sum of their individual prebiotic properties.

Applicant respectfully submits that Moro, Boehm, Rigo and Lesens, either viewed individually or in any combination, fail to disclose or suggest a composition that encompasses the subject matter as set forth in amended claim 1, as well as the claims that are dependent therefrom.

The Moro and Boehm references share three common authors, disclosed similar findings and were published around the same period by the same scientific institution. Both Moro and Boehm studied the bifidogenic effects of an oligosaccharide mixture on faecal flora and stool characteristics of preterm infants. To do this, an oligosaccharide mixture consisting of 90% GOS and 10% FOS was supplemented into a standard pre-term infant formula at a concentration of 10 g/L. The object of combining the oligosaccharide mixture and the pre-term infant formula by

Moro and Boehm is to "mimic the molecular size distribution of human milk oligosaccharides" and to "benefit from a possible synergistic effect of both [FOS and GOS] compounds to stimulate the growth of *Bifidobacteria*." Moro at page 292. While Moro, Boehm and Rigo aimed to mimic the contents of breast milk, Lesens, on the other hand, intended her frozen dessert composition to promote the growth of beneficial gastrointestinal bacteria.

In addition, Applicant has previously noted that Lesens, Boehm and Rigo fail to suggest a synergistic effect of FOS and GOS on the growth of any species of beneficial bacteria. Moro, while noting the possibility of a synergistic effect of FOS and GOS, reported results that do not support such an effect on *Lactobacilli*. The number of *Lactobacilli* also increased significantly in both groups fed the supplemented formulas (versus placebo,  $P < 0.001$ ), but there was no statistically significant difference between the group fed formula with 0.4g/dL oligosaccharides and the group fed formula with 0.8 g/dL oligosaccharides." See Moro's Abstract.

With respect with Boehm, the results obtained support the lack of a synergistic effect. "*Lactobacilli* were also detectable in all infants at the study entry. There was a significant increase in all groups during the course of the study period but there was no significant effect on the diet (data not shown). Neither was there a significant effect of the oligosaccharide supplement on the counts of *Bacteroides*, *Clostridium* species, *E. coli*, *Enterobacter*, *Citrobacter*, *Proteus*, *Klebsiella*, and *Candida*. Boehm at page F180, left column, third full paragraph.

In Rigo, the growth and quality of growth of term infants fed with a New Formula (NF) were similar to those seen in infants that were fed with breast fed and conventional formulas. The composition of the New Formula includes prebiotic substances such as FOS and GOS wherein the total amount together is 0.4 g/100 ml; partially hydrolyzed whey protein and  $\beta$ -palmitate. According to Rigo, the "use of prebiotic substances in NF resulted in a rapid and significant increase in the percentage of endogenous bifidobacteria and the ability to maintain a stable intestinal flora during the first months of age." Rigo at page 39.

In addition, Lesens, like Moro, Boehm and Rigo, fails to suggest the use of an oligosaccharide blend of FOS and GOS, wherein the weight ratio FOS:GOS is from about 0.5 to about 20.

Based on the remarks presented hereinabove and in light of the claim amendments herein, Applicant respectfully submits that Moro, Boehm, Rigo and Lesens, either individually or in combination, fail to render claims 1, 5, 7-8 and 10-11 obvious. None of these references disclose or suggest the claimed composition, as set forth in amended claim 1, as well as claims 5, 7-8 and 10-11, which depend therefrom. Accordingly, Applicant earnestly requests the Examiner to reconsider and withdraw the rejection of these claims based on Moro, Boehm, Rigo, in view of Lesens.

As noted, the subject matter of claim 3 has been incorporated into independent claim 1, thereby cancelling claim 3. Accordingly, the cancellation of claim 3 renders the rejection of this claim moot.

On pages 8-10 of the Office Action, the Examiner rejected claims 1 and 26 under 35 U.S.C. §103(a), as being unpatentable over Lesens, in view of U.S. Patent Application Publication No. US2003/0138476A1 to Van Leeuwen et al. (referred hereinafter as “Van Leeuwen”). According to the Examiner, Van Leeuwen “teach[es] nutritional preparations such as baby food or enteral food (abstract) which include prebiotics such as fructo-oligosaccharides and galacto-oligosaccharides and further glutamine or an equivalent such as is known in the art (pg. 1, [0013-0014], pg. 2, [0017].” In addition, the Examiner contended that Van Leeuwen claims a nutritional preparation as a nutritional preparation with also contains glutamine or equivalent thereof and further prebiotics such as galacto-oligosaccharides and fructo-oligosaccharides (claims 1-3, 8, and 12). Based on the combined teachings of Lesens and Van Leeuwen, “it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the compositions as taught by Lesens et al. with glutamine as taught by Van Leeuwen et al.” In addition, the Examiner asserted that “one of ordinary skill in the art would have been motivated to combine the teachings since both teach nutritional compositions that help the intestinal tract and provide fibers such as prebiotics” (GOS and FOS). Furthermore, there is “a reasonable expectation of success” when adding “glutamine of Van Leeuwen et al. to the compositions of Lesens et al.” Applicant respectfully traverses the rejection.

Applicant respectfully submits that Lesens and Van Leeuwen, either taken individually or in combination, fail to disclose or suggest the claimed composition as set forth in amended claims 1 and 26. More specifically, Lesens and Van Leeuwen fail to disclose or suggest a



composition that contains an oligosaccharide blend of FOS and GOS, wherein the weight ratio of FOS:GOS is from about 0.5 to 20 and wherein such combination has a synergistic effect at lower FOS dosages.

The disclosures of Lesens and the claimed invention are both discussed in the above-mentioned sections.

Van Leeuwen's invention relates to the "use of glutamic acid for the preparation of a nutritional preparation that is intended for use for the treatment or prevention of excess or undesired permeability of the intestinal wall. See Van Leeuwen's Abstract. The nutritional preparation can be "combined with suitable prebiotics and probiotics, which have a beneficial effect on the intestinal flora. The prebiotics comprise short or long chain oligosaccharides, in particular galacto-oligosaccharides and fructo-oligosaccharides..." Van Leeuwen at page 2, paragraph [0017]. However, Van Leeuwen, similar to Lesens, fails to disclose a composition that contains a pharmaceutical blend of FOS and GOS, wherein the weight ratio of FOS and GOS is from about 0.5 to about 20, the subject matter of which is encompassed in amended claims 1 and 27. Van Leeuwen, as well as Lesens, also fails to suggest a synergistic effect of FOS and GOS on the growth of *Lactobacilli*, such that their combined prebiotic property is greater than the sum of their individual prebiotic properties. Accordingly, Van Leeuwen fails to cure the deficiency of Lesens to enable one of ordinary skill in the art to make or use the claimed composition of the present invention. Moreover, even if Van Leeuwen is combined with Lesens, one of ordinary skill in the art would still not arrive at the claimed composition because both of these references fail to disclose or suggest the claimed composition as set forth in both amended claims 1 and 26. See MPEP 2143.03 ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art").

Furthermore, Applicant respectfully submits that the Office Action has failed to establish any motivation to combine Lesens and Van Leeuwen. The Federal Circuit has repeatedly emphasized that evidence of a motivation to combine must accompany a challenge based on multiple references. See *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999) and *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed. Cir. 1998). See also MPEP §2143.01 (The prior art must suggest the desirability of the claimed invention). A statement that combination of the prior art

to meet the claimed invention would have been within the ordinary skill in the art is not alone sufficient to establish a *prima facie* case of obviousness.

Accordingly, Applicant respectfully submits that claims 1 and 26 are not obvious over Lesens and Van Leeuwen. Applicant earnestly requests the Examiner to reconsider and withdraw the rejection of these claims under § 103(a).

Based on the amendments and remarks presented hereinabove, Applicant respectfully submits that the rejections based on lack of novelty and obviousness have been overcome. Applicant earnestly requests the Examiner to reconsider and withdraw all of her rejections based on 35 U.S.C. § 102(b) and §103(a).

### CONCLUSION

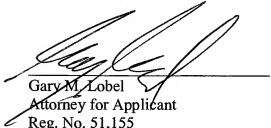
For at least the reasons set forth above, this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicant's representative designated below.

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.17 which may be required to Deposit Account No. 19-0134 in the name of Novartis.

If a telephone interview would be of assistance in advancing the prosecution of the application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

Respectfully submitted,

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